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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,486	02/24/2004	Russell A. Houser	019001	1784

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,486

Applicant(s)

HOUSER ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings have hand-drawn portions. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities: the abstract is too long (168 words).

4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 21-24, 27-30 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schmitt (US Patent 6,375,662).

7. Regarding Claim 21-23, Schmitt'662 discloses a patch to pace against tissue containing a layer of biocompatible material (26, see column 4, line 64 to column 5, line 6) and a layer of nitinol, a biocompatible superelastic/shape memory material (40, see column 8, lines 19-35).

8. Regarding Claim 24, Schmitt'662 discloses that the patch can use the shape memory material to take up any shape in the resting state depending on the application of the patch (column 8, lines 36-50).

9. Regarding Claim 27 and 28, Schmitt'662 discloses that the layer of superelastic/shape memory material is at least partially covered with a matrix of biocompatible material (column 4, line 64 to column 5, line 6).

10. Regarding Claim 29 and 30, the device taught by Schmitt'662 is capable of being used to compress a hollow body cavity, such as the heart, because of its size and use of biocompatible materials.

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11. Regarding Claim 34, Schmitt'662 discloses the incorporation of a medicinal substance into the patch (column 7, lines 5-10).
12. Regarding Claim 35, the device taught by Schmitt'662 is capable of compressing tissue because it has the same structure as the disclosed device.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662, as applied to Claim 21, and in further view of King, et al. (US Patent 3,874,388).**

16. Schmitt'662 teaches the limitations of Claim 25, except for the use of protrusions extending from the shape memory material.

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17. King'388 teaches a patch (9) having multiple arms (91) configured to have a concave shape (see Figure 1c) in order to close a hollow chamber of the heart with a simple and reliable structure that does not require open-heart surgery (column 2, lines 45-57). King'388 also teaches that the arms (91) have bars at the ends (83, 93) to allow the patch to be anchored to the heart (column 6, lines 14-31). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to include barbs on the end of the arms to ensure that the patch can be anchored to the body.

18. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and King'388, as applied to Claim 25, and in further view of Forber, et al. (US Patent 5,733,294).

19. Schmitt'662 and King'388 disclose the limitations of Claim 26, except for the use of a power source.

20. Forber'294 discloses an occlusion apparatus with the use of an external electricity source to cause the arms (60) of a device to repel each other (column 6, lines 45-57). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use an external electricity source to cause the arms to repel each other in order to uniformly distribute themselves.

21. Claim 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662, as applied to Claim 21, in further view of Zhu, et al. (US Patent 6,589,269).

22. Schmitt'662 teaches the limitations of Claim 31, except for an explicit structure of a deployment device.

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23. Zhu'269 teaches a patch delivery system containing a deployment section (20) configured to apply a vacuum to retain the patch until ready for delivery and a handle (102) (column 3, lines 55-65). Zhu'269 discloses a deployment device because it is necessary to deliver the patch to parts of the body that are not readily accessible.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to disclose a deployment device for use with a patch that uses a vacuum because a vacuum can releasably hold the patch.

24. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662, as applied to Claim 21, in further view of Evard, et al. (US Patent 5,536,251).

25. Schmitt'662 teaches the limitations of Claim 32, except for the use of jaws to deploy the patch.

26. Evard'251 teaches that it is known to use jaws (32) to apply a patch (column 3, lines 66 to column 4, lines 3) because this is less invasive than performing open heart surgery. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a jaw to apply a patch to the heart rather than apply it manually because it does not require the risks of open heart surgery.

27. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662, as applied to Claim 36, in further view of King'388.

28. Schmitt'662 teaches the limitations of Claim 37, except for that the patch has a concave shape with multiple arms with protrusions extending from the arms.

29. Regarding Claim 37, King'388 teaches a patch (9) having multiple arms (91) configured to have a concave shape (see Figure 1c) in order to close a hollow chamber of the heart with a simple and reliable structure that does not require open-heart surgery (column 2, lines 45-57). Regarding Claim 38, King'388 also teaches that the arms (91) have bars at the ends (83, 93) to allow the patch to be anchored to the heart (column 6, lines 14-31). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to include barbs on the end of the arms to ensure that the patch can be anchored to the body.

30. Claims 39, 41, 45, 47, 48, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 in further view of Zhu'269.

31. Regarding Claim 47 and 51, Schmitt'662 discloses a method of applying a patch which includes retaining the patch inside a deployment device (column 3, lines 11-14), advancing the deployment device to the tissue surface (column 2, line 67 to column 3, line 3 and column 3, line 19-20), pressing the patch against the tissue surface (column 3, lines 20-21), manipulating the deployment device to allow it close the opening (column 3, lines 20-22). The patch includes a layer of biocompatible material, that is capable of swelling, and a layer of superelastic/shape memory material (see Claim 1 rejection). Regarding Claim 45, Schmitt'662 the incorporation of a medicinal substance into the patch (column 7, lines 5-10).

32. Zhu'269 teaches a patch delivery system using a deployment section (20) configured to apply a vacuum to retain the patch until ready for delivery and a handle (102) (column 3, lines 55-65). Zhu'269 discloses the use of a deployment device

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because it is necessary to deliver the patch to parts of the body that are not readily accessible and the vacuum allows the body party to be covered with the patch to be cleared of blood first (column 4, lines 32-46). Regarding Claim 48 and 49, Zhu'269 discloses that this method can be performed on internal organs (column 4, lines 5-11). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to disclose a deployment device for use with a patch that uses a vacuum because a vacuum can remove excess blood.

33. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and Zhu'269, as applied to Claim 39, in further view of Hammerslag (US Patent 5,653,730).

34. Schmitt'662 teaches the limitations of Claim 39, except for the use of an adhesive.

35. Hammerslag'730 teaches that it is known to use adhesives to deploy patches because it aids in preventing hemorrhaging (column 2, lines 7-47). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use adhesives when deploying a patch in order to prevent hemorrhaging.

36. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and Zhu'269, as applied to Claim 39, in further view of Evard'251.

37. Schmitt'662 teaches the limitations of Claim 32, except for the use of jaws to deploy the patch.

38. Evard'251 teaches that it is known to use jaws (32) to apply a patch (column 3, lines 66 to column 4, lines 3) because this is less invasive than performing open heart

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surgery. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a jaw to apply a patch to the heart rather than apply it manually because it does not require the risks of open heart surgery.

39. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and Zhu'269, as applied to Claim 39, in further view of King'388.

40. Schmitt'662 and Zhu'269 teach the limitations of Claim 43, except for the use of arms, a base, and attachment means.

41. King'388 teaches the use of a patch (9) containing arms (91), a base (84), an attachment means extending from the arms (87), and advancing the deployment device to the tissue surface of the heart (Figures 9a-9k and column 1, lines 5-10) in order to repair a septal defect. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a patch containing arms, a base, and an attachment means because it is able to fit into a catheter and deployment through a catheter is poses less risk to the patient (column 2, lines 31-57).

42. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and Zhu'269, as applied to Claim 39, in further view of Zhu'269.

43. Schmitt'662 and Zhu'269 teach all the limitations of Claim 39. Regarding Claim 46, Zhu'269 teaches that the patch is used to compress tissue in a patient to stop bleeding (column 4, lines 24-25). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use the patch to apply pressure in order to stop bleeding.

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44. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt'662 and Zhu'269, as applied to Claim 47, in further view of King'388.

45. Schmitt'662 teaches the limitations of Claim 50, except for the use of attachment means extending from the patch.

46. King'388 teaches a patch (9) having multiple arms (91) configured to have a concave shape (see Figure 1c) in order to close a hollow chamber of the heart with a simple and reliable structure that does not require open-heart surgery (column 2, lines 45-57). King'388 also teaches that the arms (91) have bars at the ends (83, 93) to allow the patch to be anchored to the heart (column 6, lines 14-31). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to include barbs on the end of the arms to ensure that the patch can be anchored to the body.

Double Patenting

47. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

48. **Claims 21-28, 31-33, and 36-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-16, and 18-20 of U.S. Patent No. 6,726,696.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are less specific than the claims in the patented case, specifically, the application claims a patch containing a layer of biocompatible material and a layer of biocompatible superelastic/shape memory material while the patented case claims a patch containing a layer of biocompatible polymer (which is a biocompatible material), a layer of biocompatible superelastic/shape memory material (exactly the same), and a layer of polymer (which can be present, but is not necessary in the device claimed in the application).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Imb

A handwritten signature in black ink, appearing to read "M. J. Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER